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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
AEDER, SEAN E	
ART UNIT	**PAPER NUMBER**
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/856,940	TEMSAMANI ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) *2,3 and 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☒ Claim(s) *1 and 4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The Amendments and Remarks filed 9/10/07 in response to the Office Action of 3/8/07 are acknowledged and have been entered.

Claims 1-6 are pending.

Claims 2, 3, and 5 are withdrawn.

Claims 1 and 4 have been amended by Applicant.

Claims 1 and 4 are currently under examination.

The following Office Action contains NEW GROUNDS of rejections necessitated by Amendments that *substantially* broadened the scope of the claims under examination.

Objections Withdrawn

The objections to claims 1 and 4 are withdrawn.

Rejections Withdrawn

The rejections under 35 U.S.C. 112, second paragraph, are withdrawn.

The rejection under 35 U.S.C. 112, first paragraph, is withdrawn.

The provisional rejection, on the ground of nonstatutory obviousness-type double patenting over claims 22-23 of Application No. 10/336312, is withdrawn due to the abandonment of Application No. 10/336312.

Specification

The specification remains objected to for the reasons stated in the Office Action of 3/8/07. The Office Action of 3/8/07 contains the following text:

"The specification is objected to on page 4, 5, 9, 14, and 15 for improper disclosure of polypeptide sequences, as it fails to comply with the requirements of 37 CFR 1.821 through 1.825. This definition sets forth limits, in terms of numbers of amino acids and/or numbers of nucleotides, at or above which compliance with the sequence rules is required. Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. (see MPEP 2422). Proper correction is required."

In the Reply of 9/10/07, Applicant states that there is an intention to file a Supplemental Response to specifically address this outstanding issue.

Response to Arguments

Double Patenting

Claims 1 and 4 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 28 of copending Application No. 10/490357, for the reasons stated in the Office Action of 3/8/07 and for the reasons set-forth below. Although the conflicting claims are not identical, they are

not patentably distinct from each other because claim 28 of 10/490357 recites a species of pending claims 1 and 4.

In the Reply of 9/10/07, Applicant states that claim 28 of 10/490357 recites the limitation "...wherein said composition is substantially free of solvent". Applicant argues that claims 1 and 4 do not recite, and the instant specification does not disclose, a composition "...wherein said composition is substantially free of solvent". Applicant further argues that "...wherein said composition is substantially free of solvent" is not meant to be read into the instant claims.

The arguments found in the Reply of 9/10/07 have been carefully considered, but are not deemed persuasive. In regards to arguments that the compositions of the instant claims are not limited to those compositions that are substantially free of solvent, the specification of 10/490357 does not *define* which compositions would be deemed substantially free of solvent. Without defining what is meant by "substantially free of solvent", "substantially free of solvent" does not impart a specific limitation upon claim 28 of 10/490357. Therefore, claim 28 of 10/490357 recites a species of pending claims 1 and 4.

New Objections

Claim 1 is objected to for awkwardly reciting: "...said peptide comprising a formula (I) BXXBXXXXBBBXXXXXXB (I), wherein:...". It is suspected Applicant intended claim 1 to recite: "...said peptide comprising ~~a formula (I)~~ BXXBXXXXBBBXXXXXXB ~~(I)~~ **(formula (I))**, wherein:...". Proper correction is required.

Claim 4 is objected to because there appears to be an article missing before "Composition". Claim 4 recites: "Composition according to claim 1,...". It is suspected Applicant intended claim 4 to recite: "~~Composition~~ **The composition** according to claim 1,...". Proper correction is required.

New Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, claim 1 is inclusive of a genus of peptides comprising a formula BXXBXXXXBBBXXXXXXB, wherein a B group includes an amino acid residue in which the lateral chain comprises a basic group and an X group includes an aliphatic or aromatic amino acid residue. It is noted that claim 1 broadly encompasses variant peptides with no common structure or function. For instance, it is noted that the peptides merely require "a" single amino acid residue in which the lateral chain comprises a basic group and "a" single aliphatic or aromatic amino acid residue.

Further, the peptides of claim 1 broadly encompass *every* peptide with an amino acid residue in which the lateral chain comprises a basic group and an aliphatic or aromatic amino acid residue.

The specification discloses and reasonably conveys peptides comprising a formula BXXBXXXXBBBXXXXXXB, wherein each B in the formula consists of an amino acid residue in which the lateral chain comprises a basic group and each X in the formula consists of an aliphatic or aromatic residue (page 7, in particular).

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to that genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d, 2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of sequences that encompass the genus of peptides nor does it provide a

description of structural features that are common to the genus. Further, in regards to a genus encompassing variants, Applicant is directed to Example 13 of the Synopsis of Application of Written Description Guidelines (http://www.uspto.gov/web/menu/written.pdf), which addresses claims drawn to a genus of polypeptide variants. Example 13 states that even when a specification discloses that changes which produce variants are routinely done in the art, the specification and the claims do not provide any guidance as to precisely what changes should be made. Structural features that could distinguish the compounds of the claimed genus from others not encompassed by the genus are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is needed. Since the disclosure fails to describe common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of peptides comprising a formula BXXBXXXXBBBXXXXXXB, wherein each B in the formula consists of an amino acid residue in which the lateral chain comprises a basic group and each X in the formula consists of an aliphatic or aromatic residue is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the

'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of peptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolation. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Pastan et al (US Patent 5,608,039; 3/4/97).

Claim 1 recites: "A pharmaceutical composition for treating and/or preventing cancer comprising at least one anti-cancer agent bonded to at least one peptide, said peptide comprising a formula (I) BXXBXXXXBBBXXXXXXB (I), a B group includes an amino acid residue in which the lateral chain comprises a basic group, and an X group includes an aliphatic or aromatic amino acid residue, wherein a retro form of said formula (I) peptide comprises D and/or L configuration amino acids, or a fragment of said amino acids comprising a sequence of at least 5 and, preferably, at least 7 successive amino acids of said formula (I) peptide". It is noted that recitation of "wherein a retro form of said formula (I) peptide comprises D and/or L configuration amino acids, or a fragment of said amino acids comprising a sequence of at least 5 and, preferably, at least 7 successive amino acids of said formula (I) peptide" does not limit the peptides encompassed by claim 1. Further, as noted above, the peptides of claim 1 merely require "a" single amino acid residue in which the lateral chain comprises a basic group and "a" single X aliphatic or aromatic amino acid residue. Further, the peptides of claim 1 broadly encompass *every* peptide with an amino acid residue in which the lateral chain comprises a basic group and an aliphatic or aromatic amino acid residue.

Pastan et al teaches a pharmaceutical composition for treating and/or preventing cancer comprising at least one anti-cancer agent bonded to at least one peptide, said peptide comprising a formula (I) BXXBXXXXBBBXXXXXXB (I), a B group includes an amino acid residue in which the lateral chain comprises a basic group, and an X group

includes an aliphatic or aromatic amino acid residue, wherein a retro form of said formula (I) peptide comprises D and/or L configuration amino acids, or a fragment of said amino acids comprising a sequence of at least 5 and, preferably, at least 7 successive amino acids of said formula (I) peptide (see lines 55 of column 2 to line 29 of column 3 and amino acid sequence of Figure 2, in particular).

Summary

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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